K062057 1/2

AUG 0 2 2006

510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

Date Prepared:	July 19, 2006
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	David D. Cox, Ph.D. Senior Principal Regulatory Affairs Specialist
Telephone Number:	(763) 391-9251
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II. Device Information:

Trade Name:	U-CLIP™
Common Name:	Implantable clip
Classification Name:	Clip, Implantable
Classification:	Class II, 21 CFR 878.4300
Product Code:	FZP
Predicate Device:	Coalescent Surgical U-CLIP™ 510(k) No. K031623, Reg. No. 878.4300; Product Code: FZP

Device Intended Use: The Surgical U-CLIP™ is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including cardiovascular and coronary artery bypass grafting procedures; including use in cardiovascular and coronary artery bypass grafting procedures.

U-CLIP™ Device, Model NC65

Device Description: The U-CLIP™ device is a self-closing clip for anastomosis and tissue and prosthetic material approximation or attachment applications. The Model NC65 U-CLIP™ device consists of a self-closing Nitinol clip that is constrained in an open position in a stainless steel hypotube until released by the surgeon after placement. The clip is released from a slot in the side of the hypotube. This design allows precise placement of clips prior to closure, and facilitates an interrupted "suture" technique by eliminating knot tying. The device is manufactured with a standard implantable grade of Nitinol.

Intended Use: The U-CLIP™ Device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.

Contraindications: Do not use for tubal ligation.

Comparison to Predicate Device(s): The U-CLIP™ device is substantially equivalent to the U-CLIP™ devices cleared in K031623, K024366, K060400, K023125, K021407, K013664, K012317, K994160, and K971588 in terms of materials, use and application. The new clip utilizes a different way of constraining and releasing the implantable Nitinol Clip with stainless steel hypotubes, releasing the clip from a slot in the side of the hypotube as opposed to releasing the clip from the end of the hypotube.

Test Data: Verification and validation testing confirms that functional characteristics are substantially equivalent to the predicate device cited. This included clip strength and clip deployment angle. All test data obtained satisfied the documented product and performance specifications.

Summary: Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the NC65 U-CLIP™ included in this submission has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Medtronic Cardiac Surgery
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Senior Principal Regulatory Affairs
Specialist
7601 Northland Drive
Minneapolis, Minnesota 55428-1088

Re: K062057
Trade/Device Name: NC65 U-CLIP
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: July 19, 2006
Received: July 20, 2006

Dear Dr. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062057

Indications for Use

510(k) Number (if known): K062057

Device Name: **NC65 U-CLIP**

Indications for Use:

The U-CLIP™ Device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.

Prescription Use _X_ AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062057